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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Art Unit: 1761
Dov HARTAL et al) Examiner: C. Sherrer
Appln. No.: 09/449,093) Washington, D.C.
Date Filed: November 29, 1999) Confirmation No. 5856
For: NATURAL COLORING PRODUCTS) ATTY.'S DOCKET: HARTAL=1B

DECLARATION UNDER 37 CFR 1.132

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Dov Hartal, hereby solemnly declare as follows:

I am the same Dov Hartal who is the first named inventor and applicant of the above-identified application. Attached to this declaration is my *curriculum vitae* which forms an integral part of the present declaration.

I am familiar with the prosecution history of this application and of the various prior art documents applied against our claims. Based on my personal knowledge and experience in the present field, and taking into account the disclosures of all the prior art documents applied against our claims by the U.S. patent examiner, I can say in confidence that there are unique aspects of the present invention, as well as a unique result, as have been explained during the

Noting about innovation

prosecution of our above-identified patent application and its predecessors, and as is confirmed below.

I make the following statements based on my personal knowledge and/or experience as statements of fact:

1. Gentle over-all treatment and breaking of the tomato into its component parts is essential according to our invention of the above-identified U.S. patent application.

Lycopene oxidizes easily when exposed to air. In the ripe tomato, lycopene crystals are locked in tiny chromoplasts which protect them. Conventional processing inevitably uses elevated temperatures and equipment that causes mechanical damage to the chromoplasts and results in the oxidation of large portions of the exposed lycopene. In production of the coloring material according to our invention, we employ mild, i.e. gentle, conditions that assure minimal damage to the protective chromoplasts and to the lycopene in them. Thus, we avoid equipment such as positive displacement pumps, and agitation in presence of air. Fine grinding as in the Dale citation, etc. that causes mechanical damage to the chromoplasts should be prevented. We avoid high temperatures and prolonged heating and exposure to air.

2. Centrifugation is a gentle process and will not destroy the chromoplasts to any significant degree.

3. Ripe tomatoes contain about 60 ppm up to as much as 100 ppm of lycopene, and about 5% soluble solids (4.5-5.5° Bx).

4. Commercial tomato products are mostly pasteurized, and the pasteurization operation, particularly in series or simultaneously with rough (as opposed to gentle) sequencing from the tomato to the final product will inevitably destroy all or substantially all of the chromoplasts, and accelerate the oxidation of lycopene, whereby the results of the present invention are impossible. Pasteurization involves heating above 80°C (time depends on the pH and nature of the product).

5. Tomato juice is a commercial product which has been subjected at least to pasteurization. Commercial tomato juice has a Bx of about 4.8 to 5.2, and not higher than about 7, with a lycopene content far below 500 ppm, i.e. no more than about 100 ppm, and these values are inconsistent with our invention in which the resultant coloring material has a soluble solids concentration below 5°Bx and 500-3,000 ppm of lycopene content. *no claim chromoplasts*

6. Tomato paste is about a six fold concentrate of tomato juice and contains from 290 ppm up to as much as 350-550 ppm of lycopene and has high content of soluble solids, approximately 30°Bx, inconsistent with our invention.

7. High lycopene content tomatoes are well known. While conventional ripe tomatoes contain 60-100 ppm of lycopene, the high lycopene content tomatoes contain a lycopene content of about 160 ppm or more.

As regards the prior art, my analysis reveals the following:

(a) As regards the Graves document, it is clear that Graves is working with the liquid fraction. Graves specifically refers to "cell disruption" and this certainly means of destruction of the chromoplast membrane. *why? certain*

(b) The Brumlick citation discusses making tomato-based or tomato flavored commercial foods and concentrates, thereby requiring at least pasteurization. *also about product here pasteurization* Also mentioned is an evaporating or distilling operation which implies even greater heating. Like Graves, Brumlick works with a liquid fraction rather than solid fraction, contrary to our invention. *claimed?*

(c) As regard the Iwatsuki publication, it is very ambiguous. It can be interpreted in different ways. Fig. 3 of Iwatsuki is unclear, but it is possible that Iwatsuki obtained a product containing a maximum of 70 ppm of lycopene as indicated in Fig. 3, which is far less than the minimum according to our invention. Another possibility is that Iwatsuki totally isolated the chromoplasts meaning that the

concentration of lycopene was far more than the maximum of 3,000 ppm according to our invention. The Iwatsuki publication is further confusing in that under the heading "Results and Discussion" appearing at page 764, the Iwatsuki method is said to involve "two principle steps: Sephadex G-25 gel filtration of tissue homogenates followed by Percoll density gradient centrifugation" which suggests that Iwatsuki et al were working on a liquid fraction rather than isolating chromoplasts from any solid fraction, again contrary to our invention.

(d) The Bradley document subjects the tomato parts to rough handling and heat, and this inevitably results in the destruction of the chromoplasts and in oxidation of lycopene. This document states that the chopped tomatoes "are heated to inactivate enzymes", and this will inevitably destroy chromoplasts.

(e) With respect to the Dale citation, what is disclosed is a so-called "hot break" in all five of the Dale systems, the chopped tomatoes having been heated to 90°C.) This will inherently and inevitably result in destruction of the chromoplasts.

(f) The Lang citation mentions treatment of tomato by either a "cold break" method or "hot break" method. The cold break method involves temperatures of 65-70°C and the hot

break method involves temperatures of at least 95°C. The temperature must be sufficiently high, according to the Lang citation, to deactivate the pectolytic enzymes in the tomatoes. Following what Lang says to do will result in destruction of the chromoplasts.

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By: _____



Date: _____

May 22, 2003



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Curriculum Vitae Dr.Dov Hartal

PERSONAL

Born in 1936. Married. Father to two daughters and a son.

ACADEMIC BACKGROUND

Ph.D. University of Illinois, Urbana, Ill. U.S.A.

M.Sc. University of Illinois, Urbana, Ill. U.S.A.

B.Sc. Technion, Haifa, Israel.

EMPLOYMENT

1992 - Present; Managing Director of Hartal R&D Ltd. Initiator and in charge of R&D of the Lycopene project from its beginning in Koor Foods through pilot stage in Makhteshim Chemical Products, to industrial production by LycoRed Natural Products Industries. Several patent applications were submitted as result of his work.

1980 - 1992; Division Head, Koor Foods Research & Development, Member of the Management Committee, Koor Foods Group. Played crucial role in devising strategy for the group and its constituent factories. Was responsible for evaluation and coordination of technology projects and the representative of Koor Foods Group in technological and scientific forums.

1969 - 1980; Chief Food Technologist for Vita company. Was responsible for quality assurance, new product and process development. Represented Vita and the Israel Manufacturers Association in various professional committees.

1974 - 1980; Assistant Professor in Food Technology in the Agricultural Faculty of the Hebrew University.

1967 - 1969; Senior Research Food Scientist, General Mills, Minneapolis. Minn. U.S.A. As a result of his work, General Mills submitted four patent applications.

DIRECTORSHIPS

included Teva Pharmaceuticals, Dekel Edible Oil Industries, Keren Electronics, Institute of Food Microbiology and the institute for Quality & Control.

HONORS

Appointed University of Illinois Fellow in Food Science. Awarded Scholarship by the Haifa Chapter of Rotary Club

Member in the following Honor Societies: Sigma Xi, Phi Kappa Phi and Gamma Sigma Delta.

AFFILIATIONS

Professional Member of the Institute of Food Technologists. Member of the Israel Society of Food & Nutrition Sciences and the Association of Chemical Engineers.

Chairman of several technical and scientific committees.

MILITARY SERVICE

Honorably discharged from the Israel Defense Forces with the rank of Captain.

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